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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,483	07/18/2003	Andy C. Neilson	FSII 308	4564

23581 7590 03/30/2007
KOLISCH HARTWELL, P.C.
200 PACIFIC BUILDING
520 SW YAMHILL STREET
PORTLAND, OR 97204

EXAMINER

SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
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1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/623,483	Applicant(s) NEILSON ET AL.	
	Examiner Arlen Soderquist	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1-8-04 and 1-21-05</u> . | 6) <input type="checkbox"/> Other: ____ |

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1. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).
2. The attempt to incorporate subject matter into this application by reference to the book Digital Image Processing and the article by Bob Sinclair is ineffective because the references are publications and it is not proper to incorporate essential material by reference to publications.
3. The disclosure is objected to because of the following informalities: the current status of all non-provisional applications needs to be updated.

Appropriate correction is required.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-19 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenhard (US 6,881,584) in view of Beaudette, Harter or Gerding. In the patent Lenhard teaches infrared thermography for measuring real-time thermogenesis in organisms and cells. The described invention relates, in general, to thermography and, in particular, to a method of using IR thermography to monitor physiological and molecular events that elicit a thermogenic

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response in animals (including humans), plants, tissues, cells and cell-free systems. The method can be used for screening, identifying, and ranking drug candidates for multiple diseases, disorders and conditions. The summary of the invention contains a number of methods that essentially recite measuring the temperature of one or more samples with infrared thermography, contacting the one or more samples with an agent that is to be tested, measuring the temperature of the one or more samples resulting from the contacting step with infrared thermography, and comparing the two sample temperature for the one or more samples. A difference between the two temperatures being taken as the test agent having cause a thermodynamic change in the sample. Figure 1 shows a system for imaging infrared thermogenesis in a number of samples. Columns 8-14 teach various aspects of the device and method relative to its performance in the device of figure 1. Of note are the use of multiwell plates having either a 96-well or 384-well format (column 8, lines 1-6) and the types of test agents and effects that are monitored. The examples give more details on the thermography apparatus (column 16), types of microtiter plates that were found to be optimum for the different experiments and methods to reduce thermal noise and reflectivity from outside effects. Examples 2-4 show the effects of different test substances of cell suspensions. Examples 8-10 show different types of reactions including enzymatic and binding reactions. Lenhard does not teach means to add the test substances to the samples allowing for a period of thermal equilibration prior to addition of the test agent to the sample.

In the paper Beaudette describes an improved method for obtaining thermal titration curves using micromolar quantities of protein. Two simple modifications of a commercially available microcalorimeter allow rapid and accurate equilibration of sample with titrant and result in increased sensitivity. The modifications permit the rapid equilibration of the reaction vessel vapor space with solvent vapor and unambiguous determination of the temperature difference between the thermostat and the contents of the reaction vessel. A procedure is described for performing a thermal titration under conditions in which the system is undergoing a continuous thermal drift. The procedure is used to determine the standard enthalpy and free energy changes for the binding of ADP to bovine liver glutamate dehydrogenase. Only 0.3 μmol of protein sample was required. The observed values ($\Delta H^{\circ} = -13.0 \text{ kcal mol}^{-1}$, $\Delta G^{\circ} = -7.4 \text{ kcal mol}^{-1}$) agree within 5% of the values determined by S. Subramanian et al (1975). The first full

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paragraph of page 695 teaches that in order to minimize experimental errors, the sample and titrant should be at the same temperature in thermal equilibrium with the water bath. In order for this to happen the sample and titrant are allowed to equilibrate prior to contacting with each other. the last full paragraph of page 695 teaches overcoming a temperature baseline problem by introducing water saturated air into the reaction vessel to have the air at the same chemical potential as the sample. The first full paragraph of page 696 teaches the equilibration for a minimum of 15 minutes.

In the paper Harter teaches an adaptation of a micro calorimeter. The sensitivity of the Calvet Microcalorimeter makes feasible the measurement of very small heats of reaction. This capability is particularly useful when studying adsorption reactions at solid-solution interfaces. The instrument must be specially adapted for measurements of this type, since it contains no provision for equilibration and mixing of separate solutions. Previously developed adaptations of the instrument are not satisfactory because they either do not stir the combined solutions adequately to overcome flocculation problems or their mechanical energy input is high. An instrument has been developed whereby 2 solutions can be equilibrated in the calorimeter cell, then mixed and stirred with a net mechanical energy input of -2 ± 0.4 mcalories. This instrument makes possible the precise measurement of very small heats of reaction.

In the paper Gerding presents the design and testing of a reaction calorimeter for enthalpy studies on complex formation. A constant temperature environment reaction calorimeter equipped with a device for the successive addition of known varying amounts of a solution containing either a metal ion or ligand is described in detail. The system is electrically calibrated and the temperature is measured with a thermistor. After each single experiment the calorimeter is brought back to the initial temperature by blowing a pre-cooled gas through a built-in cooler. Test measurements of the heat of neutralization of KOH by HCl, the heat of solution of KCl, and the heat of dilution of HCl gave satisfactory agreement with literature data. The temperature sensitivity is $\pm 1 \times 10^{-4}$ degrees, corresponding to an accuracy of ± 0.02 cal. or $\pm 0.2\%$ of the heat of reaction, which ever is larger. The time of equilibration of the system is < 3 minutes. Figure 2 and its associated discussion teach the pipette used that allowed thermal equilibration of the sample with the solution being added (page 2192 and the experimental procedure of page 2193).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated means into the Lenhard device and method to allow the sample and solution being added to it to come to thermal equilibrium prior to contact as taught by Beaudette, Harter or Gerding because of the advantages of having both liquids at thermal equilibrium as taught by Beaudette, Harter or Gerding.

6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lenhard in view of Beaudette, Harter or Gerding as applied to claim 19 above, and further in view of Holzwarth. Lenhard teaches the presence of thermal noise and reflectivity problems but does not use a signal modification method to correct for the effects.

IN the paper Holzwarth teaches emissivity corrections for infrared thermography. A very important prerequisite for making use of combinatorial catalysis research is a reliable, fast and efficient technique for monitoring the catalytic activities. The second full paragraph of page 17 teaches that there are problems with infrared thermography in that even though two samples can be at the same temperature, they may emit different amounts of infrared radiation. Emissivity-corrected IR thermography, which monitors the heat changes resulting from the heat of reaction on catalyst surfaces, is such a technique to handle this problem. In this article they describe emissivity-corrected IR thermography and demonstrate its performance, over time, in monitoring the catalytic activities of catalyst libraries. It is shown that not only can static relative activity be displayed, but also that catalyst-specific time-dependent properties, such as activation and deactivation phenomena can be demonstrated.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included an emissivity correction as taught by Holzwarth into the Lenhard device because of the ability to correct for differences in emitted radiation even though the samples have the same temperature as taught by Holzwarth.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art is directed toward calorimetry apparatus and method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Arlen Soderquist

Primary Examiner

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